

Office Action Summary	Application No. 09/330,909	Applicant(s) WOLFF ET AL.	
	Examiner Joseph T. Voitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,12-14,18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,12-14,18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Please note that the contact information for this application has changed. As of January 12, 2004, the Examiner of record **Joseph Woitach's** telephone number is (571) 272-0739.

This application claims benefit to provisional application 60/100,168, filed September 14, 1998; and is a continuation in part of 09/391,260, filed September 7, 1999, which is a divisional of 09/975, 573, filed November 21, 1997, now patent number 6,265,387, which is a continuation of 08/571,536, filed December 13, 1995, now abandoned.

Applicants amendment filed November 7, 2003, has been received and entered. The specification has been amended. Claims 5 and 13 have been canceled. Claims 1 and 18 have been amended. Claims 1, 2, 4, 6, 12-14, 18, 20-22 are pending and currently under examination.

Specification

The disclosure is objected to because of the following informalities:

The amendment to the specification to indicate Applicants' claim for priority is incorrect and appears to have a typographical error. Specifically, the amendment indicates that 09/391,260, filed September 7, 1999, is a divisional of **09**/975, 573, filed November 21, 1997, now patent number 6,265,387, however patent 6,265,387 arose from application **08**/975,573, filed November 21, 1997.

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Appropriate correction is required.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). Specifically, review of 09/391,260 and 08/975,573 does not fully support the instantly claimed invention. The specifications of '260 and '573 are directed to the delivery of a polynucleotide to a parenchymal cell in the liver, not cardiac tissue. Moreover, the methods taught and used are not consistent with that instantly claimed, including the use of invasive techniques and the failure to teach the use of increased hydrostatic pressure to increase the permeability of a blood vessel for the delivery of the polynucleotide to cells outside the lumen of the blood vessel. In the instant case, applications '260 and '573 are not sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112 regarding written description and enablement of the instantly claimed invention.

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Therefore, while the claim for priority to '260 and '573 is noted, and correct to the extent that the current application and the prior applications were copending, the instant application is only given priority to September 14, 1998, which is the filing date of provisional application 60/100,168 which fully supports the instantly claimed invention.

Claim Objections

Claims 1, 2, 4, 6, 12-14, 18, 20-22 objected to because the specific steps set forth in claim 1 are not clearly set forth with respect to the relationship of each of the steps is withdrawn.

The amendments to the claims consistent with that suggested language set forth in the prior office action (see page 3) has obviated the basis of the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Cancellation of the claims has rendered the rejection moot.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 6, 12-14, 18, 20-22 stand rejected under the judicially created doctrine of double patenting over claims 1-4 of U. S. Patent No. 6,627,616 B2 (issued September 30, 2003)

As indicated in the prior office action (starting at page 4) the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent

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and the application are claiming common subject matter,. More specifically, in each case the methods are generally drawn to the delivery of a polynucleotide to an extravascular cell, reciting method steps for delivery of the nucleic acids from inside a vessel into extravascular cells. In particular the use of hydrostatic pressure is specifically recited in claim 2 of '616. The use and practice of the method set forth in '616 is broad and not limited to practice in any particular tissue. Further, the specification specifically contemplates practicing the method in a variety of tissues, including cardiac tissue (starting at the bottom of column 3, line 64 and general supported at top of column 2). The practice of the method in cardiac tissue as set forth in the instant application would be an obvious and specific tissue contemplated by '616.

In response, Applicants have noted the amendment to the specification with the new claim of priority and argued that the amendment has obviated the rejection. See Applicants' amendment, middle of page 4. Applicants' arguments have been fully considered but not found persuasive.

Initially, it is noted that Applicants do not argue that the claims are not obvious each other. Further, Applicants do not indicate or argue how the new claim for priority has obviated the basis of the rejection. It is noted that each '616 and '909 now indicate a claim for priority to a similar set of non-provisional applications, however the claim of priority is insufficient to obviate a double patenting type rejection. More specifically, the instant application has one inventor in common with '616 (Jon A. Wolff) and several different inventors listed. Additionally, '616 has the designated assignee of Mirus Corporation (see reel/frame

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013749/01884) and the instant application is assigned to Wisconsin Alumni Research Foundation (see reel/frame 014049/0855). Thus, in the instant case '616 and '909 have one common inventor and no common assignee at the time of filing. Accordingly, the conflicting claims are subject to an obvious type double-patenting rejection (and rejection under 102(f)/(g)) regardless of the claim for priority. See MPEP 800, Chart II-B.

As noted above, Applicants do not traverse Examiners interpretation of the claimed inventions nor specifically provide any arguments to why the claimed inventions are not obvious over one another. Therefore, for the reasons above and of record, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1, 2, 4, 6, 12-14, 18, 20-22 rejected under 35 U.S.C. 102(e) as being anticipated by Monahan *et al.* (US Patent 6,627,616) is withdrawn.

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As noted above, the instant application has been given the priority to the filing date of provisional application 60/100,168, filed September 14, 1998. Upon close review of 6,627,616 and supporting priority documents it is found that '616 is only fully supported by provisional application 60/121,730, filed February 26, 1999. Because the priority date of the instant application is earlier than that of '616, the '616 reference does not qualify as a 102(e) type reference. Therefore, the rejection is withdrawn.

Claims 1, 2, 4, 6, 12-14, 18, 20-22 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Specifically, in the instant case the specification of Monahan *et al.*, US Patent 6,627,616 teaches methods for the *in vivo* delivery of a polynucleotide via a vessel (set forth in claim 1) and specifically contemplates the use of hydrostatic pressure to affect delivery outside the vessel (set forth in claim 2). Upon review of the disclosure of '616, the method can be used to transfect an entire animal (set forth in claim 4) or used more locally for particular tissues including the heart (column 3, line 1). Monahan *et al.* provide specific teaching anticipating each of the method steps set forth in the pending claims.

In response, Applicants respectively disagree and argue that the inventors of '616 invented the general process for intravascular delivery of a nucleic acid, and that the instant inventors invented the process for delivery to the heart. See Applicants' amendment, bottom of page 4. Applicants' arguments have been fully considered but not found persuasive.

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As set forth previously and above, the claims of '616 make obvious the general delivery steps of the instantly claimed invention. It is noted that in each case a vessel is used as a route of delivery and that the polynucleotide is delivered to cells outside the lumen of vessel, in particular with the use of hydrostatic pressure (compare claim 1 of the instant application and claims 1 and 2 of '616). Moreover, as noted above, the specification of '616 specifically teaches to use this method for the delivery to cardiac muscle cells. Applicants' arguments imply that two different methods are being claimed, however the specific method steps of each are the same. The only difference between the claims is that the instant claims are directed to delivery to the heart. Again, as noted above, delivery to the heart is specifically contemplated in '616. The current evidence of record indicates that the inventors of the invention disclosed in '616 specifically contemplated the instantly claimed invention. In addition, since the steps in the general delivery method are the same it is unclear how the claims of '616 for use in any tissue which are broader than instantly claimed (for use in cardiac tissue) would not include at least the same inventors as '616.

It is noted that the arguments of counsel cannot take the place of evidence in the record . *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716,718 (CCPA 1965). In this case, Applicants' assertion that the inventions were not invented by the same inventive entity is not consistent with what is being claimed or disclosed in each of '616 and the instant application.

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

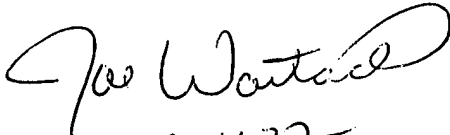
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571)272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571)272-0532.

Joseph T. Woitach


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